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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,070	01/29/2002	Thomas C. Evans	NEB-177-PUS	4532

28986 7590 08/01/2005

HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC.  
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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/937,070

Applicant(s)

EVANS ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 13, 15 and 18 is/are allowed.
- 6) ☒ Claim(s) 12, 14 and 16 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Status of the Claims***

The Amendment and Response filed 12/9/04 has been entered and considered. Claims 1-18 are pending and have been considered on the merits in this Office Action.

### ***Priority***

In light of Applicant's amendment to the Specification cross-referencing the priority applications, the conditions for receiving benefit under 35 U.S.C. 120 have been met.

### ***Specification—Objection Withdrawn***

The objection of the abstract for being too long is withdrawn in light of the amendment.

### ***Rejections Withdrawn***

#### ***Claim Rejections - 35 USC § 112***

The rejection of Claim 11 (which was intended to be a rejection of Claim 14) under 35 U.S.C. 112, second paragraph, for lack of antecedent basis for "said first and second polypeptides" is withdrawn in light of the amendment to the claim.

The rejection of Claims 1-16 and 18 under 35 U.S.C. 102(a) as being anticipated by Evans (J. Biol. Chem. (March 2000) 275(13): 9091-9094) is withdrawn in light of the correction of the benefit claim (see "Priority" above) in the present Application. The

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publication date of Evans (March 2000) is after the priority date of the present application (with priority to 60/180,319 filed Feb. 4, 2000).

### ***Rejections Maintained***

The examiner notes that the following rejection has been modified due to the amendment to the Specification changing the status of the priority in the present Application (see "Priority" above). While the reason for the rejection is the same, the rejection has been changed from a rejection under 35 U.S.C. 102(b) to 35 U.S.C. 102(a).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 12, 14, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Scott et al. (Proc. Natl. Acad. Sci. (Nov. 1999) 96(24): 13638-13643; ref. CN of IDS filed 10-12-01).

#### ***Rejection as stated in Previous Office Action:***

Scott et al. teach a method for the in vivo production of cyclic peptides and proteins. In the method of Scott et al., the C-terminal portion of the naturally split Ssp DnaE intein is fused to the N-terminus of dihydrofolate reductase (DHFR, a target enzyme) or Pseudostellarin F (a target protein) and the N-terminal portion of the Ssp

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DnaE intein is fused to the C-terminus of DHFR (see Fig. 1, 2, and p. 13640, Col. 1, 3<sup>rd</sup> paragraph) or the C-terminus of Pseudostellarin F (Fig. 2e and f and p. 13641, Col. 1, 2<sup>nd</sup> section). The fused polypeptide was reacted in vivo and resulted in the formation of a cyclic polypeptide in vivo (see p. 13641, 2<sup>nd</sup> Col., last paragraph and Table 1).

*Response to Applicants arguments:* Applicants argue that the Scott et al. reference is not prior art under 35 U.S.C. 102(b) because it was published only three months prior to the filing date of the provisional application upon which the present application claims priority. This argument has been considered and is considered persuasive in part. While the rejection under 35 U.S.C. 102(b) no longer applies due to the amendment of the present Specification which corrected the priority claim, Scott et al. is still prior art. Scott et al. (November 1999) was published before the present invention by the applicant for patent as evidenced by the filing date of the priority date of the present application (March 2000). Thus, the rejection still applies under 35 U.S.C. 102(a) for the same reasons as provided in the previous Office Action.

### ***Claim Objections***

Claim 14 is objected to for the recitation of "wherein said the target polypeptide" in lines 1-2 of the claim. Applicant should delete either "said" or "the".

Claim 17 is objected to as being dependent upon a rejected base claim (claim 12), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusions**

Claims 12, 14, and 16 are rejected. Claim 17 is objected to. Claims 1-11, 13, 15, and 18 are free of the prior art of record. The prior art of record does not teach or suggest a method identical to Claims 1-11, 13, 15, or 18.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Holly Schnizer  
July 25, 2005



KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER